JAN - 8 2004

Special 510(k) Summary of Safety and Effectiveness:
Stryker Spine Vertebral Body Support System
(Line Extension and Design Modification to the Surgical Dynamics Mesh Cage System)

Proprietary Name:	Stryker Spine Vertebral Body Support System
Common Name:	Vertebral Body Replacement Device
Proposed Regulatory Class:	Class II Spinal Intervertebral Body Fixation Orthosis, 21 CFR §888.3060
Device Product Code:	87 MQP: Spinal Vertebral Body Replacement Device
For Information contact:	Karen Ariemma Howmedica Osteonics Corp. 325 Corporate Drive, Mahwah, NJ 07430 Telephone: (201) 831-5718 Fax: (201) 831-6038 Email: kariemma@howost.com
Date Summary Prepared:	December 9, 2003

This Special 510(k) submission is intended to address design modifications and a line extension to the predicate Surgical Dynamics Mesh Cage System to create the subject device that is referred to as the Stryker Spine Vertebral Body Support System. The Surgical Dynamics Mesh Cage System consists of a cage body and endcaps. There is no change in intended use for the modified device when compared to the previously cleared device.

Intended Use:
The Stryker Spine Vertebral Body Support System implant is a device intended to replace a vertebral body or an entire vertebra. It is for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body or vertebra due to tumor or trauma (i.e. fracture). For both corpectomy and vertebrectomy procedures, the Stryker Spine Vertebral Body Support System is intended to be used with supplemental internal spinal fixation systems. The use of bone graft with the Stryker Spine Vertebral Body Support System is optional.

Statement of Technological Comparison:
The subject components share the same intended use and basic design concepts as that of the predicate device. Performance data were submitted to characterize the additional components and design modifications to the Surgical Dynamics Mesh Cage System to create the subject Stryker Spine Vertebral Body Support System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 8 2004

Ms. Karen Ariemma
Regulatory Affairs Specialist
Stryker Howmedica Osteonics
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K033837
Trade Name: Stryker Spine Vertebral Body Support System (VBOSS)
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: MQP
Dated: December 9, 2003
Received: December 10, 2003

Dear Ms. Ariemma:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Milhauser

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K033837

Device Name: Stryker Spine Vertebral Body Support System

The Stryker Spine Vertebral Body Support System implant is a device intended to replace a vertebral body or an entire vertebra. It is for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body or vertebra due to tumor or trauma (i.e. fracture). For both corpectomy and vertebrectomy procedures, the Stryker Spine Vertebral Body Support System is intended to be used with supplemental internal spinal fixation systems. The use of bone graft with the Stryker Spine Vertebral Body Support System is optional.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use ___ (Per 21 CFR 801.109)
(Optional Format 1-2-96)

for Mark N. Melkerson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K033837